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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,230	07/30/2001	Mark M. Rasenick	27611/35996A	3414

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EXAMINER	
GITOMER, RALPH J	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/918,230	RASENICK ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The IDS received 2/27/02 has been entered and claims 1-40 are currently pending in this application. Priority is granted to 7/29/00.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamada.

Kamada (Cellular and Molecular Neurobiology) entitled "Alterations of Tubulin Function Caused by Chronic Antidepressant Treatment in Rat Brain" teaches in the abstract, antidepressant treatment enhances the coupling between stimulatory G protein and the catalytic subunit of adenylyl cyclase and tubulin interaction with G. On page 110 last few lines, antidepressant treatment acts on membranes to enhance the G protein effector coupling process.

Claims 1, 2, 10, 11, 19, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasenick.

Rasenick (J Clinical Psychiatry) entitled "G Protein Mediated Signal Transduction as a Target of Antidepressant and Antibiopolar Drug Action: Evidence from Model Systems" teaches in the abstract, a mechanism to test the efficacy of suspected therapeutic agents. On page 52 second column, chronic antidepressant treatment of

rats increases coupling between Gs alpha and adenylyl cyclase. On page 54 second column first full paragraph, chronic exposure of cells to antidepressant drugs modifies adenylyl cyclase by some interaction between Gs alpha and the enzyme.

Claims 1, 2, 5, 7, 10, 11, 14, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Young.

Young (J of Affective Disorders) entitled "Lack of Effect of Antidepressants on Mononuclear Leukocyte G Protein Levels or Function in Depressed Outpatients" teaches on page 202, antidepressants stimulate G protein to enhance the coupling with adenylyl cyclase. Effects of antidepressant treatment on various cell models such as leukocytes and platelets which exhibit many biochemical processes analogous to those in neurons is known. On page 204 basal adenylyl cyclase activity in MNL membranes from depressed patients who subsequently responded to antidepressant treatment was studied.

Claims 1, 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen.

Chen (J of Neurochemistry) entitled "Chronic Treatment of C6 Glioma Cells with Antidepressant Drugs Increases Functional Coupling Between a G Protein and Adenylyl Cyclase" teaches on page 724, G proteins are the target of antidepressant actions and act at the postsynaptic membrane to increase the coupling between G proteins and adenylyl cyclase. On page 730 column 1 first full paragraph, G stimulated adenylyl cyclase was increased subsequent to chronic antidepressant exposure.

All the features of the claims are taught for the same function by the above cited references.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 4, 6, 8, 9, 12, 13, 15, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young.

Young (J of Affective Disorders) entitled "Lack of Effect of Antidepressants on Mononuclear Leukocyte G Protein Levels or Function in Depressed Outpatients" teaches on page 202, antidepressants stimulate G protein to enhance the coupling with adenylyl cyclase. Effects of antidepressant treatment on various cell models such as leukocytes and platelets which exhibit many biochemical processes analogous to those

in neurons is known. On page 204 basal adenylyl cyclase activity in MNL membranes from depressed patients who subsequently responded to antidepressant treatment was studied.

Claims 3, 4, 12, 13 differ from Young in that they specify redistribution of G protein, claims 6, 15 are directed to erythrocytes, 8, 17 are directed to platelets, and 9, 18 are directed to fibroblasts.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to expect the same assay known in leukocytes to have the same function in other cells because antidepressants are systemically administered drugs that contact all blood cells. Regarding the presently claimed redistribution of G protein, one would expect redistribution of such proteins when stimulated or inhibited by various agents.

Claims 21, 22, 32, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasenick.

Rasenick (J Clinical Psychiatry) entitled "G Protein Mediated Signal Transduction as a Target of Antidepressant and Antibiopolar Drug Action: Evidence from Model Systems" teaches in the abstract, a mechanism to test the efficacy of suspected therapeutic agents. On page 52 second column, chronic antidepressant treatment of rats increases coupling between Gs alpha and adenylyl cyclase. On page 54 second column first full paragraph, chronic exposure of cells to antidepressant drugs modifies adenylyl cyclase by some interaction between Gs alpha and the enzyme.

Claims 21 22, 32, 33 differ from Rasenick in that they specify redistribution of G protein.

It would have been obvious to one of skill in this art at the time the invention was made to redistribute G protein because such proteins when stimulated or inhibited by various agents would be expected to be found in a different distribution.

Claims 23-31, 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rasenick in view of Young.

The claims differ from Rasenick in that they are directed to determining G protein in different types of cells than Rasenick.

Young (J of Affective Disorders) entitled "Lack of Effect of Antidepressants on Mononuclear Leukocyte G Protein Levels or Function in Depressed Outpatients" teaches on page 202, antidepressants stimulate G protein to enhance the coupling with adenylyl cyclase. Effects of antidepressant treatment on various cell models such as leukocytes and platelets which exhibit many biochemical processes analogous to those in neurons is known. On page 204 basal adenylyl cyclase activity in MNL membranes from depressed patients who subsequently responded to antidepressant treatment was studied.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to expect the same assay known in leukocytes to have the same function in other cells because antidepressants are systemically administered drugs that contact all blood cells. Regarding the selection of type of cell as presently claimed for

the determination, it is noted the present specification does not compare the claimed assay in different types of cells. No unexpected results are seen and an undisclosed advantage is given little or no weight.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is directed to detecting the effectiveness of antidepressant therapy, and claim19 is directed to assaying for an agent having antidepressant activity. The specification as originally filed teaches effects of various known antidepressants upon content of G protein and resultant adenylyl cyclase activity. Further, on page 20 Table 4 shows known antidepressants change G distribution in cells. On page 22 Example 13 is directed to screening for effectiveness of antidepressant therapy and for agents having antidepressant activity, however, it is merely description with no screening having been performed, no data presented, and most importantly, no correlation between the putative mechanism of action and actual results are seen. No effectiveness of any agents nor screening for any unknown agents having been

administered is found in the specification. The leap from a putative mechanism of action to real world application based upon a mechanism of action has not been made. No new antidepressant agents have been identified. Given the known difficulty in studying antidepressant activity, the specification is not enabling for doing so.

Claims 1-18, 30-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Claim 1 is directed to a method of detecting effectiveness and may be intended to be determining effectiveness. Further, there is no step in claim 1 to determine effectiveness, a correlating step may be intended. In claim 30, "having the ability" is indefinite because compounds have activity, not ability.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
Elling (US 2002/0061599 A1) teaches G protein binding and adenylyl cyclase.
Chen (J of Pharm and Exp Ther) teaches antidepressant treatment and activated G.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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